DECLARATION

UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Jan Vijg

Serial No. 09/306,333 Art Unit: 1643

Filed: May 6, 1999 Examiner: Souaya, Jenanne E.

For: BRCA 1 and bMLHI Gene Primer Sequences And Method For Testing

Declaration of Jan Vijg

1. My name is Jan Vijg and I am the inventor of the invention described and claimed in my above identified U.S. patent application serial No. 09/306,333. My curriculum vitae accompanies herewith.

2. After studying the "obviousness" rejections regarding the claims of my said patent application, I have the following comments:

A. Naturally, it would have been obvious to use Vijg or Vijg II for attempting the discovery of new tests for detecting mutations in medically or industrially relevant genes and other DNA sequences. The test for BRCA1 is such a test. Such discovery is the main application of Vijg and Vijg II. In this respect Vijg and Vijg II are similar to an efficient procedure to genetically clone a gene, any gene. To further the analogy,

this present application applies Vijg and Vijg II to discover a new gene test that has its own unique industrial application. While Vijg and Vijg II teach a general procedure to discover new gene tests, this application presents the actual discovery of such a new gene test--i.e., for BRCA1.

B. This new gene test is novel, has industrial application (e.g., to quickly, accurately and cost-effectively establish if a woman is predisposed to breast cancer), and is non-obvious, since it is impossible to predict for one of ordinary skill in the art what such a test would look like. The latter is similar to gene discovery; i.e., all genes are DNA sequences and all have similar characteristics, albeit there is so much unexpected variation in structure and function that they all are unique and have unique applications.

C. Thus, while I agree entirely with the facts as given by the Examiner, my interpretation of these facts is different. For example, it is true that "The ordinary artisan would have had a reasonable expectation of success that using the method taught by Vijg, or Vijg I, primers could be generated that would both successfully amplify the necessary coding regions of the BRCA1 gene and provide characteristic 2-D spot patterns for certain mutations, as Vijg and Vijg II both teach in extensive detail how to prepare primers that would be successful in the method taught by Vijg given a known gene sequence and using long distance and short distance multiplex PCR".

The fact remains, however, that the eventual BRCA1 test discovered according to Vijg and Vijg II is new (not disputed, I assume), has new application (it wasn't there previously to quickly and reliably diagnose women predisposed to breast cancer) and

is unexpected; i.e., non-obvious, since, similarly to a newly discovered gene, each test has its own unique characteristics that cannot be predicted by someone of ordinary skill in the art. There are now ample examples of the unique and unexpected differences among gene tests in the literature.

D. The main issue that seems to be the problem is the assumption that Vijg and Vijg II are identical to a BRCA 1 test as presented here. This is not true. While Vijg and Vijg II teach generally applicable procedures, this new application provides a gene test. This test was discovered using Vijg and Vijg II, but is really completely dissimilar and essentially different from the procedures taught in Vijg and Vijg II. Indeed, while many procedures related to gene cloning have been patented, this still does not make each newly discovered gene "obvious".

E. If this were not true, I would be able to argue (though erroneously) that since some general gene cloning patent (I think there is the Boyer patent?) teaches how to discover a new gene with industrial application, every one of such genes would be "obvious" since they all consist of DNA sequences and were discovered using the gene cloning method. However, experts would refute this on the basis that each gene has its own characteristics and would represent a unique discovery. This is exactly the case in this situation of my present application, particularly with the unique exon *11* of the BRCA1 gene, *ten times* the size ("3.4kb exon 11"--page 3 of my said patent application herein) of any gene exon ever before tested with the Vijg and Vijg II type of technique, and containing the unique "approximately 60% of the coding region" (page 3) of the BRCA1 gene.

3. I have, moreover, reviewed the accompanying Declaration of R. David Rines who has assisted me through the years in the development of my inventions of said Vijg patents and of the invention of my above-entitled application, as well. I find the facts declared therein, to be true and accurate to my personal knowledge and/or information and belief; including the descriptions of the uncontemplated manipulation and departure from my earlier procedure teachings described in my said Vijg and Vijg II patents in the making of the presently claimed invention, as set forth in paragraphs 3-8 of said Declaration. I also concur with the lack of "obviousness" of our experimentation set forth in paragraph 9. Certainly such turned out to be neither a priori certain or "obvious" to me or to my associates, individually or collectively, and I (we) created the Vijg and Vijg II procedures.

4. I have carefully reviewed method claims 10, 11, 13 and 14 as amended in the accompanying Amendment G, and also the amended kit claims 4-6, and I declare that these describe only the original invention of my above application as filed.

5. Under the provisions of 37 CFR 1.132, moreover, I declare that any disclosure in Vijg patent WO96/39535 ("Vijg") and/or in Vijg et al patent 6,007,231 ("Vijg II") of the invention specified in such amended method claims 10, 11, 13 and 14 and kit claims 4-6, was not claimed in said patents, and, indeed, was derived solely from me and not 'by another'.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are

punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: December 18, 2003

Jan Vijg

RE NS 09/306,333

CURRICULUM VITAE

Revised: October, 2003

Name: JAN VIJG

Address: 314 Branch Oak Way,
San Antonio, TX 78230

Date of Birth: June 19, 1954

Place of Birth: Rotterdam, The Netherlands

Education:

1980	B.A.	State University of Leiden, Leiden, The Netherlands
1982	M.Sc.	State University of Leiden, Leiden, The Netherlands
1987	Ph.D.	State University of Leiden, Leiden, The Netherlands

Academic Appointments:

1982-1987	Research Associate, TNO Institute for Experimental Gerontology, Rijswijk, The Netherlands
1987-1990	Head, Department of Molecular Biology, TNO Institute for Experimental Gerontology, Rijswijk, The Netherlands
1990-1996	Lecturer on Medicine, Harvard Medical School, Division on Aging, Boston, Massachusetts
1993-1998	Director, Molecular Genetics Section, Gerontology Division, Department of Medicine, Beth Israel Hospital, Boston, MA.
1996-1998	Associate Professor of Medicine, Harvard Medical School, Boston, Massachusetts
1998-	Professor of Physiology, University of Texas Health Science Center at San Antonio
1998-2000	Director of Basic Research, CTRC Institute for Drug Development, San Antonio, Texas

Other Professional Appointments:

1990-1993	Scientific Director, Ingeny B.V., Leiden, The Netherlands
1993-1995	Founding Scientific Adviser, Ingeny B.V., Leiden, The Netherlands
1996-	Member Scientific Advisory Board AphaGene, Woburn, MA
1996-1998	Chairman Scientific Advisory Board Aeiveos Sc. Gr., Seattle, WA
2000 -	Chairman Scientific Advisory Board Accelerated Genomics Inc., San Antonio, TX.
2003 -	Scientific Advisory Board Chronogen, Montreal, Canada.

Awards and Honors:

1987	Schreuder Award of the Netherlands Society of Gerontology
1987	Second Award of the European Committee of the Sandoz Foundation for Gerontological Research
1994	Nathan Shock New Investigator Award of The Gerontological Society of America

Major Committee Assignments (National and Regional):

1985-1990	Founder and Chairman of the Board (since 1987), Biomedical Study Group on the Etiology of Aging, the Dutch Organization MEDIGON (Foundation of Medical and Health Research).
1987-1990	Founder and Project Manager of the EC "EURAGE Molecular Biology Research Group"
1991	Chairman WHO Committee "Principles for evaluating chemical effects on the aged population", Geneva, 9-13 Dec. 1991.
1996	Member NASA panel, "Future of Animal Experimentation in Space Explorations".

Editorial Boards:

1988-1996	Managing Editor, Mutation Research, Section DNAging
1989-present	Reviewing Editor of the Journal "Aging"
1993-1998	Member Editorial Board Mech. Ageing Dev.
1996-present	Member Editorial Board Mutat. Res.
2000-present	Member Editorial Board Aging Research Reviews
1999-present	Editor for the Americas, Mechanisms of Aging and Development

Major Research Interests:

1. Molecular Genetics of Aging and Cancer
2. Gene Mutations and Human Genetic Diseases
3. Molecular Evolution

Symposia:

1987	Co-organizer of the Symposium "Cell Biological Basis of Aging", Veldhoven, The Netherlands.
1988	Organizer of the EURAGE Symposium "Molecular Biology of Aging", Crete, Greece.

1989 Organizer of the workshop "The Identification, Isolation and Characterization of Aging and Longevity Genes: Strategies, Technology and Funding", Nerja, Spain.

1991 Co-Organizer of the New York Academy of Sciences Meeting "Cellular Defence Systems and Aging", Modena, Italy.

1995 Organizing Committee 7th Int. Conf. Environ. Mutagens, Toulouse, France.

1998 Co-Organizer 1st Annual Meeting on Rodent Models in Modern Risk Assessment, Bar Harbor, Maine.

1998 Co-Organizer Keystone Symposium on Aging: Genetic and Environmental Influences on Life Span, Durango, Colorado.

2002 Co-Organizer International Symposium on "Functional Genomics of Aging", April 24-27, 2002, Seville, Spain.

Research Support (in the US, since 1993/1994):

1. PI for Cystic Fibrosis Foundation grant G836; total direct costs: $ 60,000; active: 1994-1996
2. PI for studies on "Mutational Mechanisms in Cancer" supported by Ingeny B.V.; total direct costs: $ 49,990; active: 1994-1995
3. PI for Project no. 1 of NIA grant PO1 1801 AG10829-01; total direct costs: $ 406,330; active: 1994-1998
4. PI for studies on "Genetics of Aging and Longevity" supported by Toyobo Co., Ltd.; total direct costs: $91,515; active: 1994-1997
5. PI for Massachusetts Dept. of Public Health grant DPH3408699D006; total direct costs: $216,378; active: 1996-1999
6. Subcontract on NIH/NCI grant P50-CA 72712; total direct costs: $36,382; active: 1999-2000.
7. Subcontract on NIH/NCI grant P30 CA 54174-08; total direct costs: $1,900,776; active: 1998-2002.
8. PI for NIH/NIA grant 1 P30 AG13314-01; total direct costs: $1,064,860; active: 1996-1999.
9. PI for NIH/NCI grant 1 RO1 ES/CA 08797-01; total direct costs: $631,967; active: 1997-2000
10. PI for NIH/NIA grant 1 PO1 AG16348-01; total direct costs: $3,124,445; active: 1999-2004
11. Subcontract on NIH NIA grant 1 RO1 CA 78564 (PI: Frederick Li); total direct costs: $150,000; active: 1999-2003.
12. Co-PI for NIH NIA grant 5 P30 AG 13319-06; total direct costs: $3,500,000; active: 2000-2005.
13. PI for NIH/NIA grant 1 RO1 AG18923-01; total direct costs: $800,000; active: 2001-2005.
14. PI for NIH/NIEHS grant 1UO1ES11044; total direct costs: $3,538,686; active: 2001-2005
15. Subcontract on European CEFIC-LRI grant; total direct costs:$716,750; active: 2001-2004.

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Peer-Reviewed Papers

1. Schaap GH, Verkerk AS, Vijg J, Jongkind JF. Flow sorting in the study of cell-cell interaction. Cytometry 1983;3:408-413.
2. Vijg J, Mullaart E, van der Schans GP, Lohman PHM, Knook DL. Kinetics of ultraviolet induced DNA excision repair in rat and human fibroblasts. Mutation Res 1984;132:129-138.
3. Vijg J, Mullaart E, Lohman PHM, Knook DL. UV-induced unscheduled DNA synthesis in fibroblasts of aging inbred rats. Mutation Res 1985;146:197-204.
4. Uitterlinden AG, Vijg J, Giphart MJ, Knook DL. Variation in restriction fragment length and methylation pattern of rat MHC class I genes. Expl Clin Immunogenet 1985;2:215-222.
5. Vijg J, Mullaart E, Roza L, Baan RA, Lohman PHM. Immunochemical detection of DNA in alkaline sucrose gradient fractions. J Immunol Methods 1986;91:53-58.
6. Vijg J, Mullaart E, Berends F, Lohman PHM, Knook DL. UV-induced DNA excision repair in rat fibroblasts during immortalization and terminal differentiation in vitro. Exp Cell Res 1986;167:517-530.
7. Gravekamp C, van den Bulck LP, Vijg J, van de Griend RJ, Bolhuis RLH. C-myc gene expression and interleukin-2 receptor levels in cloned human $CD2^+$, $CD3^+$ and $CD3^-$ lymphocytes. Nat Immun Cell Growth Regul 1987;6:28-36.
8. Mullaart E, Lohman PHM, Vijg J. Differences in DNA repair between rat skin cells in vitro and in vivo. J Invest Dermatol 1988;90:346-349.
9. Gossen JA, Vijg J. E. coli C: a convenient host strain for rescue of highly methylated DNA. Nucleic Acids Res 1988;16:9343.
10. Mullaart E, Boerrigter METI, Brouwer A, Vijg J. Age-dependent accumulation of alkali-labile sites in DNA of post-mitotic but not in that of mitotic rat liver cells. Mech Ageing Dev 1988;45:41-49.
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12. Boerrigter METI, Mullaart E, van der Schans GP, Vijg J. Quiescent human peripheral blood lymphocytes do not contain a sizable amount of pre-existent DNA single-strand breaks.Exp Cell Res 1989;180:569-573.
13. Gille JJP, Mullaart E, Vijg J, Leyva AL, Arwert F, Joenje H. Chromosomal instability in an oxygen-tolerant variant of Chinese hamster ovary cells. Mutation Res 1989;219:17-28.
14. Mullaart E, Roza L, Lohman PHM, Vijg J. The removal of UV-induced pyrimidine dimers from DNA of rat skin cells in vitro and in vivo in relation to aging. Mech Ageing Dev 1989;47:253-264.

15. Gille JJP, van Berkel CGM, Mullaart E, Vijg J, Joenje H. Effects of lethal exposure to hyperoxia and to hydrogen peroxide on NAD(H) and ATP pools in Chinese hamster ovary cells. Mutation Res 1989;214:89-97.
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17. Uitterlinden AG, Vijg J. Two-dimensional DNA typing. Trends in Biotechnol 1989;7:336-342.
18. Uitterlinden AG, Slagboom P, Knook DL, Vijg J. Two-dimensional DNA fingerprinting of human individuals. Proc Natl Acad Sci USA 1989;86:2742-2746.
19. Gossen JA, de Leeuw WJF, Tan CHT, Lohman PHM, Berends F, Knook DL, Zwarthoff EC, Vijg J. Efficient rescue of integrated shuttle vectors from transgenic mice: A new model for studying mutations in vivo. Proc Natl Acad Sci USA 1989;86:7971-7975.
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24. Uitterlinden AG, Vijg J. Denaturing gradient gel electrophoretic analysis of the human cHa-ras1 proto-oncogene. Appl Theoret Electrophoresis 1990;1:175-179.
25. Slagboom PE, DeLeeuw WJF, Vijg J. Messenger RNA levels and methylation patterns of GAPDH and ß-actin genes in rat liver, spleen and brain in relation to aging. Mech Ageing Dev 1990;53:243-257.
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Patents

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2. J. Vijg and J.A. Gossen: Process for the rescue of DNA and for detecting mutations in marker genes (US patent 013198).

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5. E. Mullaart, A.G. Uitterlinden and J. Vijg: Two-dimensional electrophoresis apparatus and electrophoresis unit therefor (International PCT nr. NL93/00191).

6. J. Vijg and D. Li: Method of and apparatus for diagnostic DNA testing (US patent 5814491; 9/29/98).

7. J. Vijg and M.E.T.I. Boerrigter: Method of and test kit for mutagenesis testing (US patent 5,817,290).

8. J. Vijg: Method of computer aided automated diagnostic DNA test design, and apparatus therefor (US patent 6,007,231).